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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,031	02/12/2002	Louis J. Theodore	690022.53656C21	7937

500 7590 10/01/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,031

Applicant(s)

THEODORE ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) The prior art cited on the Information Disclosure Statement filed February 12, 2002 is noted. However, copies of the prior art cited on this statement are not present in the parent application S.N. 09/316,452 and have not yet been considered by the examiner. Applicants are requested to provide information as to where the cited documents can be found (i.e. in which prior application(s) the prior art was provided) to aid the Office in finding and considering the cited art. Applicants are further advised that it is possible that the cited prior art may not be available in the files of the parent(s) applications (prior art removed upon issuance of a patent) and that new copies may need to be provided.

2) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3) Claims 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-35 are product claims which improperly contain process limitations, i.e. "reacts with...". For claim 31, it is unclear from the claim language whether what is being claimed is a compound which is capable of being reacted with "an anion-forming reagent" or if a compound is being claimed wherein the reaction between the "compound to be charge modified" and the "anion-forming reagent" has already occurred. It would appear that product by process language may be appropriate, i.e. "the charge-modified proteinaceous compound of claim 24 produced by the reaction of...".

4) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5) Claims 21-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gustavson et al (U.S. 5420,105).

Gustavson et al describe proteinaceous ligands which contain modifying groups such as active esters including thiophenyl esters, 2,3,5,6-tetrafluorophenyl esters and 2,3,5,6-tetrafluorothiophenyl esters; maleimide groups; and groups such as $-\text{COOH}$, $-\text{SO}_3^-$, $-\text{PO}_3^{2-}$, and $-\text{OPO}_3^{2-}$. See col. 16, lines 7-20 and 56-59. The modified proteins of Gustavson et al are the same compounds as the "charge-modified proteinaceous compounds" of the instant claims and therefore the compounds of the prior art anticipate the compounds of the instant claims. The "serum half-life" and "shift in isoelectric point" limitations of the dependent claims are considered to be inherent characteristics of the modified proteins of the reference in the absence of evidence to the contrary.

6) Claims 21-29 and 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al (U.S. 5,648,059).

Gray et al describe proteinaceous ligands which contain modifying groups such as active esters including tetrafluorophenyl esters, tetrafluorothiophenyl esters, and N-hydroxysuccinimide esters. See col. 8, lines 17-30; col. 4, line 63 – col. 5, line 25. The modified proteins of Gray et al are the same compounds as the "charge-modified proteinaceous compounds" of the instant claims and therefore the prior art compounds anticipate the compounds of the instant claims. The "serum half-life" and "shift in isoelectric point" limitations of the dependent claims are considered to be inherent characteristics of the modified proteins of the reference in the absence of evidence to the contrary.

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7) Claims 21-29, 31-33, 35, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan, Jr. et al (U.S. 5,322,678).

The reference describes the "charge-modification" of a "targeting protein" to achieve both basic and acidic charge modification. Treatment may be effected with a variety of reagents including anhydrides and alpha halo acids. See col. 8, lines 30-61. The modification of the serum half-life of the charge-modified protein is described at col. 5, lines 18-29 of the reference. The charge-modified targeting proteins of the reference are the same as the compounds of the instant claims and therefore the prior art compounds anticipate the compounds of the instant claims. The "serum half-life" and "shift in isoelectric point" limitations of the dependent claims are considered to be inherent characteristics of the modified proteins of the reference in the absence of evidence to the contrary.

8) Claims 21-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan, Jr. (U.S. 5,635,180).

The reference describes the "charge-modification" of a "targeting protein" to achieve both basic and acidic charge modification. Treatment may be effected with a variety of reagents including anhydrides, alpha halo acids, succinimido esters, tetrafluorophenyl esters, tetrafluorothiophenyl esters, glyoxals, phosphates, sulfates, borates, carbonates, alpha halo acids, and carboxyl groups. See col. 8, lines 29 through col. 9, line 25. These are the same protein-modifying reagents described in the instant claims. The modification of the serum half-life of the charge-modified protein is described at col. 6, lines 62-65 of the reference. The charge-modified targeting proteins of the reference are the same as the compounds of the instant claims and therefore the prior art compounds anticipate the compounds of the instant claims. The "serum half-life" and "shift in isoelectric point" limitations of the dependent claims are considered to be inherent characteristics of the modified proteins of the reference in the absence of evidence to the contrary.

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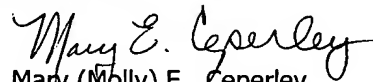
9) RIJKSUNIVERSITEIT TE GRONINGEN (WO 92/15316) [page 2, lines 6-28; page 3, lines 18-35; pages 5-8] and Jansen et al (U.S. 5,869,457) [col. 3, lines 36-49; col. 4, lines 18-38; cols. 5-9] are considered to be cumulative to the prior art cited above and are cited to further show the state of the art.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

September 25, 2003


Mary (Molly) E. Ceperley
Primary Examiner
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